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| 09/271,411      | 03/17/1999  | M. ALLEN NORTHRUP    | 22660-0009P1        | 4121             |

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EXAMINER

MARSCHIEL, ARDIN H

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/13/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/271,411**

Applicant(s)  
**Northrup et al.**

Examiner  
**Ardin Marschel**

Art Unit  
**1631**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Sep 4, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 45-71 is/are pending in the application.  
~~Claim(s) 1-44 have been canceled.~~ ~~is/are pending in the application.~~
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Applicants' arguments, filed 9/4/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### TITLE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The new title, submitted 9/4/02, is only directed to a device whereas, in contrast, both a device; with a reaction chamber, transition region, and separation region; as well as an instrument in combination with said device, as well as methods of use of same are presently claimed.

#### NEW MATTER IN THE CLAIMS

Claims 45-71 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly submitted claims 45-71 contain NEW MATTER. The NEW MATTER is present in these claims due to citing the separation practice in claim 45, part b), into bands in the separation channel without limiting the banding practice to the

utilization of PCR reaction products to produce a barcode-like result as optically imaged by a CCD camera. This CCD/PCR optical barcode-like imaging practice is present in the instant specification as filed on page 19, lines 21-22, and on page 20, lines 3-4, wherein the sample being analyzed is PCR amplification products from a PCR amplification as noted in Example 1, starting on page 17. Said pages 19 and 20 citations are within Examples 3 and 4, respectively, which are set forth on pages 18-20.

Consideration of the entirety of the instant application as filed has revealed that said Examples 3 and 4 citations are the closest and only banding (barcode-like) type arising from a PCR reaction, which is optically imaged by a CCD camera, of disclosure as filed for separation channel practice. Instant claim 60, parts e) and f), and claims 64 and 70 also contain this NEW MATTER. Claims which depend directly or indirectly from either of claims 45 or 60 also contain this NEW MATTER due to said dependence. The instant claims which are broader in scope regarding said banding practice thus include NEW MATTER due to this increased scope of banding practice now cited in the claims. This rejection is necessitated by amendment.

Additionally, newly submitted claim 56 contains NEW MATTER regarding reservoirs with electrodes partially immersed therein connected to ends of the separation channel. Consideration of the entirety of the instant disclosure as filed has revealed that

the only disclosure of partially immersed electrodes in reservoirs fluidically connected to the separation chamber is in the summary of Figure 6 in the instant specification on page 16, line 23, through page 17, line 10. This Figure 6 summary does not contain the two electrode/two reservoir/separation channel embodiment of claim 56. Rather only a three electrode/three reservoir/separation channel embodiment is described in said summary including the description of a membrane to vent gases. This description also includes channels to connect the electrodes to the reaction chamber, transition region, and terminal end of the separation region, with a filter in the transition region channel to allow only selected molecular components to pass. This summary also includes a valve to control cross-flow of fluid through a side channel. None of these reservoirs, electrodes, channels, filters, regions, chambers, etc. are disclosed as independent inventions which may optionally be included or not as desired. Thus, this summary is clearly limited to the entire assemblage which is pointed to above and not to lesser embodiments which are broader as requiring fewer electrodes, reservoirs, etc.; optionally with anything else; due to the open claim wording in claim 45, line 1, set forth as "comprising" wherein claim 56 depends from claim 45 and therefore also includes this open claim language wording due to said dependence. This broadening of claimed embodiments is NEW MATTER. This

rejection is necessitated by amendment.

#### NEW MATTER IN THE SPECIFICATION AND ABSTRACT

The amendment, filed 9/4/02, is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Applicants are required to cancel the new matter in the reply to this Office Action.

The above noted NEW MATTER in the claims regarding the generic banding practice compared to the barcode-like etc. limitations, as summarized above, has also been added to the specification in the abstract as well as in the replacement paragraph starting on page 5, line 4. This objection is necessitated by amendment.

#### VAGUENESS AND INDEFINITENESS

Claims 55 and 71 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 55 and 71 each contain the abbreviation, IEF, which causes these claims to be vague and indefinite due to lacking a full name therewith in the claims. Clarification via clearer claim wording is requested. This rejection is necessitated by

amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 45-50, 52-58, 60, and 62-70 are rejected under 35 U.S.C. § 102(e)(2) as being anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Handique et al. (P/N 6,130,098).

This rejection is applied to newly submitted claims as necessitated by amendment which replaced all previously pending claims with new claims. It is noted that this rejection is now applied also with the above newly enacted statutory basis under 102(e)(2). Handique et al. has previously been applied as an anticipatory reference for reasons set forth previously but are reiterated as appropriate below and also due to the newly submitted claim wording, as, alternatively, obvious under 35 U.S.C. § 103(a).

The abstract of Handique et al. discloses the central invention as being directed to the movement and mixing of microdroplets through microchannels in devices with reaction chambers, electrophoresis modules, etc. and methods of analysis as required in instant claims 60 etc. These elements are also summarized in column 3, line 49, through column 4, line 32, which includes various reaction and analysis practices. Inlet ports



for sample(s) and reagent(s) are disclosed in the device of the reference in column 13, lines 35-59, as also required in instant claim 53. The use of electrodes positioned in a channel so as to move liquid through channels and into a reaction chamber or separation region (instant claim 63) when a voltage potential is applied is disclosed in column 7, line 53, through column 8, line 44, which also describes flow constricting means in such channels. In order to be actuated externally as well as connected to internal fluids the electrodes are deemed as being dispositioned as required in instant claims 57 and 58. Various other flow constricting elements are present in the channels as noted in column 10, lines 57-65, which includes a valve embodiment therein noted as utilizing a "valve-seat", which is also deemed a disclosure of a membrane valve as required in instant claim 50. It is additionally noted that fluid control with sealed valves is disclosed in column 12, lines 30-44, wherein this first paragraph of the section entitled "DESCRIPTION OF THE INVENTION" also summarizes the invention of the reference. Additionally several valve usages are set forth in Figure 12 as described in column 12, lines 3-4, as well as in column 16, lines 41-61, as newly added as an instant claim limitation in all of the newly added instant claims. In column 13, lines 19-34, a device of the invention includes reaction chamber, channels which serve as transition regions connecting said chamber, and an

electrophoresis modules which is a separation region where migration data is detected regarding electrophoretic separation. Such a separation via electrophoresis is further detailed in column 21, line 35, through column 22, line 26, including optics for detecting bands from said electrophoresis separation region as required in instant claim 48 as well as disclosing fluidically connected reservoir electrodes to induce sample components to be separated into bands in the separation channel as required in part b) of instant claim 45 and in claim 56. These devices are microfabricated with the regions etc. therein reasonably interpreted as enclosed as described in column 3, line 65, through column 4, line 10, in an integrated system. Such systems of the reference may include polymeric materials as noted in column 18, lines 12-16, via polysilicon usage as also required in instant claim 54. Thermal conduction is limited in the device so that droplet movement can be controlled as noted in column 8, lines 1-9, via differential heating. This movement control is reasonably deemed to require thermal isolation in order to function at all. Without thermal isolation there would be no thermal differential by which to induce movement as described in the reference. It is noted that such flow directing means is described at numerous citations in the reference for directing flow through channels which thus includes channels from a reaction chamber to a separation chamber such as one utilizing

electrophoretic separation. See, for example, column 15, line 53, through column 16, line 23, regarding thermal isolation which supports the thermal differentials in channels. The practice of a two part device (reasonably interpreted as a device in combination with an instrument as in instant claim 46) with electrical pads as needed in a second or appliance type of element is disclosed in column 13, lines 49-59. The presence of heaters in the substrate are also described in a two part device as noted in column 18, line 40, through column 19, line 44. The heating in order to initiate a reaction such as occurring in a reaction chamber is described in column 9, lines 39-41. A reaction chamber with integral heaters arrayed along a channel can define a reaction chamber therein as disclosed in the bridging sentence between columns 16 and 17 of the reference as also required in instant claim 47. Side channels with flow control may also be utilized in the device (as in instant claim 49) of the invention as disclosed in column 14, line 24, through column 15, line 19. The practice of performing nucleic acid amplification in a reaction chamber, as in instant claim 62, is disclosed in the reference firstly in column 4, lines 14-16, and in more detail in column 9, line 56, through column 10, line 16. Thus, in summary the reference by Handique et al. discloses the above noted limitations of the instant invention.

It may be interpreted that the above descriptions within

Handique et al. are assembled from many options within the reference. Such options are clearly described as pointed out above regarding the newly submitted claims but may be also interpreted as being specific options within a generic listing of such descriptions and thus properly rejected as the instant invention is available in the reference as an obvious set of choices of device, instrument, and method limitations in the reference. This interpretation thus results in this rejection as being alternatively applied under 35 U.S.C. § 103(a) in that species or selectable limitation options in a reference are deemed motivated as suggested within a generic disclosure thus making the instant invention an obvious choice in the reference. Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the limitations of the instant invention as a specie of option selections within a more generic disclosure as in Handique et al. thus resulting in the practice of the instant invention as detailed above regarding specific limitations which are both in the reference as well as instantly claimed.

Claims 45-50, 52-58, 60, and 62-70 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Handique et al. (P/N 6,130,098), taken in view of Wilding et al. (P/N 5,587,128), or, alternatively, Wilding et al. (P/N 5,587,128), taken in view of Handique et al. (P/N 6,130,098).

Handique et al. has been summarized above as disclosing the basics of the instant invention focusing in particular on the practice of electrodes for movement of sample in microchannels between various chambers and/or regions of a microscale reaction/analysis device. Handique et al. utilizes microfabrication for the production of the devices therein in microscale practice, but only describes utilizing a specific polysilicon polymeric material molded for such device production, but without more generic polymeric material usage. This rejection is necessitated by amendment due to newly submitted claims which required new considerations as discussed above regarding Handique et al. as a prior art reference.

Wilding et al. also describes devices and production thereof for microscale reaction/analysis practice and has previously been cited in the prosecution history of this application as citing reaction chamber, transition region, and separation region elements for such devices and therefore is of the same subject matter type as the above noted Handique et al. invention. It is noted that Handique et al. may be viewed to motivate the usage of electrode/voltage induced sample flow in channels as an improvement over Wilding et al., or, alternatively, the device microfabrication practice of Wilding et al. may motivate the usage of other materials which are equivalent for microfabrication of such devices as of the Handique et al. type.

In Wilding et al. in column 7, lines 22-38, microfabrication of devices of this microscale or mesoscale type is suggested and motivated to be equivalently usable when made by silicon photolithography wherein the silicon may be polysilicon, polyimide, etc. as well as produced via plastic molding. Thus, a reasonable expectation of success in producing such devices and thus describing the devices per se is set forth for polymeric molding of devices of this type.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to either improve the Wilding et al. microscale devices and production thereof with electrode/voltage induced sample flow through channels as suggested in Handique et al., or, alternatively, produce or practice the electrode/voltage invention of Handique et al. with various microfabricated polymeric materials as equivalent as described in Wilding et al. to thus result in a reasonable expectation of success to practice the device and/or combination of device with appliance substrate of the instant invention or production thereof.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

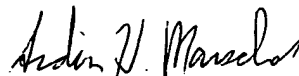
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 7, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER